

K960563

APR 29 1996

**SECTION THREE--SUMMARY OF SAFETY AND EFFECTIVENESS**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)**  
**February 8, 1996**

**I. General Provisions:**

Submitter's Name and Address: SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, Minnesota 55311

Contact Person: Connie J. Del Toro  
(612) 494-2656

Classification Name: Catheter Guide Wire

Common or Usual Name: PTCA Guide Wire

Proprietary Name: SCIMED<sup>®</sup> Sceptor<sup>™</sup> Guide Wire  
SCIMED<sup>®</sup> Sceptor<sup>™</sup> Exchange Guide Wire

**II. Name of Predicate Devices:**

SCIMED<sup>®</sup> Sceptor<sup>™</sup> PTCA Guide Wire  
SCIMED<sup>®</sup> Sceptor<sup>™</sup> PTCA Exchange  
Guide Wire  
SCIMED<sup>®</sup> ChoICE<sup>™</sup> PTCA Guide Wire

**III. Device Description:**

The Sceptor and Sceptor Exchange Guide Wires utilize common biocompatible materials and are constructed in a similar manner as currently marketed devices. The one piece stainless steel core wire has a PTFE (gray or black) coated proximal section and a tapered distal section. The distal section is surrounded by a Pebax<sup>®</sup> sleeve and platinum spring coil. The spring tip and polymer sleeve are coated with XTRA<sup>™</sup> (silicone) coating.

**IV. Intended Use:**

The SCIMED Sceptor and Sceptor Exchange PTCA Guide Wires are intended to facilitate the placement ~~and exchange~~ of PTCA balloon catheters and other therapeutic devices during angioplasty. The devices are provided sterile and intended for one procedure only.

**V. Summary of Technological Characteristics:**

The Sceptor and Sceptor Exchange PTCA Guide Wires utilize the same materials and method of construction as the currently marketed Sceptor and Sceptor Exchange Guide Wires. This 510(k) describes the use of an alternate proximal coating (PTFE) which is used on the currently marketed SCIMED ChoICE PTCA Guide Wire.

**VI. Non-clinical Test Summary:**

Testing and evaluation of the guide wires included teflon coating adherence. Test results verified that the Sceptor and Sceptor Exchange Guide Wires met the minimum requirements and are adequate for their intended use. The Sceptor and Sceptor Exchange PTCA Guide Wires are considered to be substantially equivalent to guide wires currently marketed by SCIMED (Sceptor, Sceptor Exchange and ChoICE Guide Wires) based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.